Claim 1 is directed to a method of treating Down Syndrome, and claims 15-23 are directed to methods of identifying Down Syndrome in a fetus. Applicant submits that claims 1 and 15-23 are not obvious over the Hoffmann reference in view of the Galjaard reference. Specifically, these references, when combined, do not teach or suggest all of the limitations of the currently pending claims. For example, the combination of Hoffmann and Galjaard does not teach or suggest treating or identifying Down Syndrome by analyzing a profile of all of the metabolites in a specimen, and identifying a number of metabolic abnormalities in order to either treat or identify Down Syndrome. Using the claimed methods, chromosomal abnormalities such as Down Syndrome, as opposed to single gene mutations, may be identified and treated. In comparison, Galjaard teaches the diagnosis of specific metabolites to diagnose single gene mutations.

Based upon the foregoing amendments and remarks, Applicant respectfully submits that the application is in condition for allowance. If the Examiner feels that at telephone interview would assist the Examiner in resolving any issues necessary to pass this case to issue, the Examiner is encouraged to contact Applicant's undersigned representative at (949)567-2300.

Respectfully submitted,

LYON & LYON LLP

Dated: November 9, 2001

By: 

Polaphat Veravanich
Reg. No. 45,179

PV/am
Lyon & Lyon LLP
633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(949) 567-2300

MARKED VERSION OF AMENDED CLAIM 1

1. (Twice Amended) A method of treating Down Syndrome [a chromosomal abnormality] in a fetus by identifying and treating abnormal levels [performing a comprehensive biochemical analysis] of a plurality of metabolites in a specimen of bodily fluid having metabolites from a patient, comprising:

obtaining a patient profile of [a] all [plurality] of the metabolites contained in the specimen by measuring the level of each of the [plurality of] metabolites in the specimen, wherein the patient profile comprises the level of each respective metabolite,

generating a control profile of the metabolites contained in the specimen, [biochemical characterization of the chromosomal abnormality in the fetus,] wherein the control profile [characterization] comprises [a list of each of the plurality of metabolites of the patient profile, measured during the obtaining step, with] the level for normal patients of each respective metabolite in the patient profile, wherein the normal patients comprise patients who do not have Down Syndrome,

[analyzing] comparing the patient profile with the control profile [the plurality of metabolites of the patient profile with respect to a control profile of the metabolites, the control profile being representative of normal levels of the metabolites,] by identifying each of the [plurality of] metabolites of the patient profile having a different level in comparison with the [normal] level of that metabolite for the control profile in order to identify a plurality of metabolites having different levels, wherein the comparing step comprises: [and]

determining if a formiminoglutamic acid level of the patient profile is less than a formiminoglutamic acid level of the control profile to analyze a level of mono-carbon in the patient profile relative to a level of mono-carbon in the control profile.

determining if a homocysteine level of the patient profile is increased relative to a homocysteine level of the control profile to analyze the level of homocysteine in the patient profile,

determining if a normetanephrine level of the patient profile is increased relative to a normetanephrine level of the control profile to analyze the level of normetanephrine in the patient profile,

determining if an oxalic acid level of the patient profile is decreased relative to an oxalic acid level of the control profile to analyze a level of vitamin B6 in the patient profile relative to a level of vitamin B6 in the control profile,

determining if a serine level of the patient profile is decreased relative to a serine level of the control profile to analyze the level of serine in the patient profile, and

determining if a tetra-hydro-biopterin level of the patient profile is decreased relative to a tetra-hydro-biopterin level of the control profile to analyze the level of tetra-hydro-biopterin in the patient profile, and

prescribing a supplement [biochemical treatment] for each respective metabolite of the plurality of metabolites of the patient profile having a different level when compared with the [normal] level of that metabolite for the control profile, wherein the supplement restores the level of the metabolite of the patient profile to the level of that metabolite for the control profile, and wherein the plurality of metabolites of the patient profile having different levels in comparison to the control profile identify a presence of Down Syndrome.